provided by canceled claim 20. No new matter has been added by any of the claim amendments herein.

In their response to the restriction requirement mailed March 2, 2001, Applicants elected to prosecute claims drawn to a method of making and/or using a laminate (Group I). The claims as amended herein continue to recite and involve a method of using a laminate as a barrier against ethylene oxide, and Applicants submit that the amended claims remain within the scope of elected Group I. As such, the amended claims do not constitute an impermissible shift. Accordingly, entry of the Amendments and continued prosecution of the pending claims is respectfully requested.

II. Rejection under 35 U.S.C. § 103(a)

Claims 1-10 are rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over US 3,442,686 to Jones ("Jones") in view of US 3,967,728 to Gordon et al. ("Gordon"). The Examiner alleges that Jones discloses a method of using a laminate as a barrier against gases. The Examiner acknowledges that Jones does not disclose sterilization with ethylene oxide. The Examiner relies, therefore, upon Gordon for a disclosure that materials to be gas sterilized need to be impermeable to sterilizing gases such as ethylene oxide. The Examiner concludes that it would have been obvious to combine Jones and Gordon to obtain the claimed invention.

Applicants submit that there is no suggestion or motivation to combine Jones and Gordon in the manner the Examiner has combined these references to allegedly obtain the invention of amended claim 1.

A. Jones does not provide any motivation or suggestion t use the laminate in medical applicati ns requiring sterilization.

The primary reference to Jones is directed to a low permeability packaging film. The film consists of an inorganic glassy barrier composition sandwiched between an organic base film and a sealable topcoat (col. 2, lines 38-41). The preferred inorganic materials for the glassy barrier composition include non-metallic materials such as oxides of silico n (col. 4, line 34-35).

As acknowledged by the Examiner, Jones does not disclose or suggest the use of the laminate as a barrier material against ethylene oxide gas. Furthermore, Jones does not disclose or suggest the use of the laminate as a barrier material in a medical packag e. There is no teaching or suggestion whatsoever by Jones that the laminate is useful or suitable for medical applications. Jones is also silent regarding the ability of the laminate to protect the sterility of a substance enveloped by the laminate, and whether the laminate is stable against very reactive gases such as ethylene oxide.

The only uses disclosed by Jones for the laminate are pipes, tubing, and printed and decorated non-woven webs (col. 7, lines 48-60). In view of this limited list of uses, there is no suggestion to one of ordinary skill in the art to use the laminate as a barrier material in medical storage packages, and the person of ordinary skill would not be motivated t o use the laminate for sterile applications.

B. Gordon discloses a catheter package comprising a gas impermeable metal or aluminum foil.

Gordon is directed to a catheter package containing a pouch of lubri cant 17. The catheter package and the outer surface of the pouch of lubricant are disclosed to be preferably gas

impermeable since sterilizing gases such as ethylene oxide may be deleterious to the pouch of lubricant (col. 3, lines 45-48).

Specifically, as shown in Figure 4, Gordon discloses the upper and lower walls of the lubricant-containing pouch **17** is formed from two laminated sheets: an interior thermoplastic film **35**, e.g., polyethylene or polypropylene, which is laminated to a gas impermeable outer material **36**, such as ***a metal or aluminum foil*** (col. 2, lines 45-50).

With reference to Figure 6, the upper and lower walls of the catheter pouch **17** have a four layer construction wherein the two inner layers are the same as shown in Figure 4 (col. 4, lines 18-28). Therefore, as shown in Figure 6, the order of layers beginning with the interior layer of either the upper or lower wall of the catheter pouch **17** is as follows: (a) thermoplastic film; (b) ***a metal or aluminum foil***; (c) a polyethylene layer; and (d) a Mylar layer as the outer most layer (col. 4, lines 28-33). The polyethylene layer bonds the Mylar layer to the foil layer. The Mylar film functions to reduce heat transfer to the foil in order to prevent thermal breakdown or degradation of the foil (col. 4, lines 30-45).

In summary, therefore, Figures 4 and 6 of Gordon disclose a pouch **17** made from a gas impermeable metal or aluminum foil (col. 2, lines 49-50). Gordon neither discloses nor suggests that materials other than metals could be successfully used as barrier materials. With specific reference to the claimed invention, there is especially no mention that inorganic oxides such as silicon oxide could be used successfully as a barrier material. It is extremely well known by those of ordinary skill in the art that metals (such as aluminum foil) and inorganic oxides (such as silicon oxide) have entirely different physical and chemical properties, and that these materials cannot be interchanged in various applications (such as laminates) without potentially impacting or impairing the applications.

Applicants take this opportunity to correct a statement made by the Examiner in the Office Action. The Examiner incorrectly states on page 4 of the Office Action that the barrier layer in Figure 6 is made of Mylar (polyester). In fact, it is not the Mylar which provides the barrier properties, but the *foil* layer. As disclosed by Gordon, the purpose of the Mylar layer is to reduce heat transfer to the foil and to thereby avoid thermal degradation of the lubricant, and not to serve as a barrier to a sterilizing gas.

Furthermore, amended claim 1 is directed to a method of sterilizing a storage package containing a medical instrument having a ***hydrophilic*** outer surface coating. In use, the sealed container is opened, e.g., by the application of pressure, to release the wetting fluid into the interior of the sterilized package. The sterilized medical device is allowed to soak in the sterile wetting fluid to wet the hydrophilic surface and activate the inherent low-friction properties of the hydrophilic coating.

In contrast to the claimed invention, Gordon discloses a catheter that is not pre-coated with a hydrophilic outer surface coating. There is no suggestion or appreciation by Gordon that a hydrophilic surface on the medical instrument could be used advantageously to facilitate insertion of the instrument into the body. Rather, the surface of the catheter disclosed by Gordon does not have any coating at all. The pouch 17 of Gordon contains a lubricant which, upon disruption of the pouch, is discharged over the tip 20 of the catheter to lubricate or reduce the surface friction of the catheter tip. As such, Gordon is silent as to the properties of the catheter surface, and neither discloses nor suggests that any particular catheter surface or coating is to be used or preferred. Even if there was a suggestion to combine the cited references, which Applicants contend there is not, the combination of references would not result in the claimed invention.

For all of the foregoing reasons, Applicants submit that there is no motivation to combine the cited references.

- Jones does not suggest that the laminate is suitable for sterile applications and for use as a barrier material in medical applications;
- Gordon requires the use of a metal or aluminum foil as the gas impermeable material;
- Gordon does not suggest the use of "non-metal" laminates in medical applications requiring sterilization;
- there is no motivation or suggestion to replace the pouch 17 material of Gordon which is characterized by a gas impermeable metal or aluminum foil with the "non-metal" laminate of Jones; and
- the combination of Jones and Gordon would not result in the claimed invention.

Accordingly, withdrawal of the rejection under 35 U.S.C. § 103(a) is respectfully requested.

U.S. Patents 5,942,408; 5,653,090; 3,839,078; and 5,322,161 have been cited by the Examiner as allegedly representing the state of the art. Applicants submit that none of these publications disclose or suggest the claimed invention.

CONCLUSION

Upon entry of this Amendment, claims 1-10 remain pending. Applicants respectfully submit that claims 1-10 are in condition for allowance, which action is earnestly solicited. Authorization is hereby given to charge any fee which may be due in connection with this communication to Deposit Account 23-1703.

Dated: April 1, 2003

Respectfully submitted,

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Amendments- Versi n with markings to show changes made

1. (Thrice amended) A method of using a laminate as a barrier material against ethylene oxide gas, the method comprising the steps of:

providing a storage package which contains a medical instrument having a hydrophilic outer surface coating, and a sealed container which contains a sterile wetting fluid for wetting the hydrophilic coating of the instrument,

wherein the container is formed of a [forming the] laminate having an inner layer comprising a polyolefin, an outer layer comprising a polyester, a polyolefin or a polyamide and an intermediate layer comprising a silicon oxide, and

wherein the laminate is substantially impermeable to ethylene oxide gas; [.] and

exposing the storage package [laminate] to ethylene oxide gas [,wherein the laminate is substantially impermeable to ethylene oxide gas].

5. (Thrice amended) The method according to claim 1, wherein the medical device is a urethral catheter for bladder drainage [silicon oxide-containing intermediate layer is a layer of silicon oxide deposited in-between the facing surfaces of the inner and outer layers].